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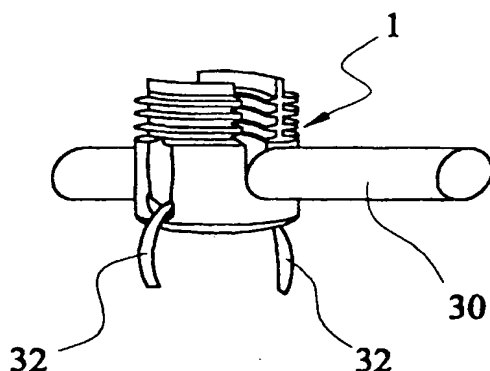
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SURGICAL FIXINGS



(57) Abstract: The invention provides an improved spinal fixing particularly suited for fixing by wires to the spine so as to provide a number of fixing locations for a support member or rod which extends along the spine. In particular, the fixing is in the form of a flat white cylinder base with two upright elements extending therefrom so as to define a channel between them. The channel has parallel sides in its upper portion, and a semi-circular profile in its lower portion, with the channel extending through the fastener from one side to the other. A slot for receiving a wire for fixing to the spine is provided perpendicular to the slot. The fixing is easier to fix and re-tension compared with prior art techniques.

WO 02/09604 A1

SURGICAL FIXINGS

This invention concerns improvements in and relating to fixings, particularly but not exclusively for locating, supporting, stabilising or correcting elements relative to spines.

A variety of conditions call for the introduction of a supporting element which spans a number of the vertebrae in a spine. The supporting element may be used to support a spine which is incapable of supporting itself entirely and/or to apply a corrective force to a spinal deformity. The supporting element generally consists of a resilient rod or other elongate element which is configured to the desired profile and then held in place relative to the spine by fixings.

A variety of fixings have been used in mounting the element relative to the spine. Pedical screws are known which are introduced into the vertebrae with a view to forming a resilient mount for the supporting element which is introduced into the head portion of the screw and fastened there by a retaining element.

It is also known to provide hook style fixings which hook on to a portion of the spine and which provide a head portion into which the supporting element is located.

In certain situations, however, the use of these fixings is undesirable or impracticable and as a result, a length of wire is used to locate the supporting element. The wire is wrapped around the supporting element and also wrapped around the spine and tightened into position by twisting and other actions. Unfortunately, the vertebral body rotation control provided by such wire fixings is limited. To provide a satisfactory initial fixing sufficient tension must be introduced to the wire. Unfortunately it is often necessary to re-tension a fixing once adjacent fixings have been positioned. This is a

-2-

difficult and awkward task with such wires. The wires are also susceptible to movement, slippage and loosening during subsequent use with the result that the support element is free to move, to an extent, relative to the spine. The full benefits of the support element are lost as a result.

The present invention, amongst other aims, aims to provide a fixing for fastening a support element in relation to a spine using wires which is convenient to use, is easy to re-tension, and / or offers improved control over vertebral body translation, coupled with the potential to apply compression and distraction forces to better control vertebral body rotation, resulting in improved correction of spinal deformity.

According to a first aspect of the invention we provide a fixing for use in retaining an element relative to a spine, the fixing providing a location at which the element is retained and an engagement location for means used to fix the fixing relative to the spine.

According to a second aspect of the invention we provide a kit, for use in fixing an element relative to a spine, the kit comprising :

- means for fixing a fixing to the spine;

- a fixing providing an engagement location for the means for fixing the fixing to the spine and a location at which the element is retained;

- means for retaining the element at the location on the fixing; and

- an element.

The first and/or second aspects of the invention may include the following options, possibilities or features. The third aspect of the invention may employ in the method a fixing and/or element and/or means for retaining and/or

-3-

means for fixing according to the first and/or second aspect of the invention, potentially including the options, possibilities or features set out below.

The fixing may be provided with a base portion. The base portion may be cylindrical. Preferably the base portion provides a surface which contacts the spine in use. The contact surface is preferably flat.

The fixing may have a generally cylindrical external profile throughout.

The fixing may have one or more, preferably two, portions extending from the base. The portions preferably extend in the same direction and are preferably parallel to one another and/or parallel to the axis of the fixing. Preferably the portions are mirror images of one another.

Preferably the retaining location for the element is provided between the portions extending from the base. More preferably the retaining location for the element is defined by a surface defined by the extending portions and base of the fixing. The retaining location may be provided in a channel through the fixing. The channel may be open, most preferably in the direction away from the base of the fixing. The sides of the channel are preferably linear, ideally parallel, and are more preferably defined by the portions extending from the base. The bottom of the channel may be curved, for instance to join one side of the channel to the other. The curved portion preferably defines the retaining location. The curved portion may be semi-circular in profile. Preferably the bottom of the channel has a corresponding profile/cross-section to the element retained.

The fixing may be provided with one or more portions which cooperate with means for retaining the element at the location. The cooperation may be a threaded cooperation. The fixing may be provided with one or more externally threaded portions and/or one or more internally threaded portions. For instance, a threaded portion may be provided

-4-

on one or both of the portions extending from the base, internally and/or externally.

The means for retaining the element at the location on the fixing may close the channel, particularly an open top thereof, upon introduction to the fixing. The retaining means may be introduced into the channel, for instance a cylindrical plug. The retaining means may be introduced around the fixing, for instance as a nut or ring. The retaining means preferably apply a force to the element towards the base of the fixing and/or towards the spine and/or towards the retaining location.

The engagement location may be provided by a channel through the fixing, and in particular through one or both of the portions extending from the base. Preferably the channel is a closed channel, and in particular a channel closed by the upper part of the portions extending from the base. The through channel preferably extends through the fixing on a single axis.

The channel may comprise an aperture in a first of the portions extending from the base and an aperture in the second of the portions extending from the base, most preferably with the apertures being linked by a groove in the base of the fixing. The groove preferably extends along the same axis as the apertures. The groove may have a semi-circular cross-section or extend from less than half a circle in cross-section. The groove may have a cross-section defined by a radius. The groove may have a cross-section configured to correspond to the profile of the means for fixing the fixing to the spine.

The aperture through one or both portions extending from the base of the fixing may have a cross-section which tapers inwards towards the base. The cross-section may be defined by a first radius and a second radius. Preferably the two radii are linked by linear portions, most preferably tangents to the two radii defined portions. Preferably the

-5-

radius furthest from the base of the fixing is greater than the radius nearer the base of the fixing.

The means for fixing the fixing to the spine may be one or more lengths of an elongate component, such as wire. The elongate component is preferably deformable, but resilient. Preferably a single component is used. The component may be tied to a part of the spine and/or wrapped around a part of the spine. In particular the wire may be applied to the laminar arch of the posterior elements of a vertebrae. This may be achieved, for instance, by passing the wire between the bony element and the dura of the spine.

The element may be a support element for the spine and/or a stabilising element for the spine and/or a correcting element for the spine. The element may be fixed to the spine at one or more, and preferably four or more, locations. One or more of the locations may employ fixings according to the first aspect of the present invention. Where a plurality of fixings are provided, one or more of the fixings may be a pedical screw, hook or wire direct to element type fixing, in addition to a fixing according to the first aspect of the present invention.

The element may be an elongate element, such as a rod or bar.

Suitable materials for the fixing and/or retaining means and/or element and / or means for fixing the fixing include metallic materials, including stainless steel, titanium alloy, commercially pure titanium, cobalt chrome alloys and others. Preferably two or more of the fixing and / or retaining means and / or elements are made of the same material, and most preferably all of the components are made of the same material.

Preferably the channel forming the engagement location has a depth of between 60% and 90% of the corresponding dimension of the means for fixing the fixing to the spine,

-6-

more preferably the depth is between 70% to 80% of the corresponding dimension.

According to a third aspect of the invention we provided a method of fixing an element relative to a spine, the method comprising:

obtaining access to a location on the spine at which the element is to be fixed;

providing a fixing in proximity with the location and fixing the fixing to the location using means for fixing;

introducing the element into proximity to the fixing and retaining the element relative to the fixing.

The element may be released from the fixing subsequently, its position relative to the fixing and/or tension adjusted or varied and then be retained once more. The fixing may act as a temporary tensioner and/or temporary position definer during the introduction of the element to a plurality of fixings.

According to a fourth aspect of the invention we provide a method of treating at least a portion of a spine, the method providing two or more fixings according to the method of the third aspect and/or one or more fixings according to the third aspect and at least one alternative form of fixing, the method further providing an element which is introduced to the fixings and retained by the fixings, wherein the position of the element in a fixing and/or the tension in the element between two fixings is different between a first instance at which the element is retained relative to the fixing and a second instance at which the element is retained relative to the fixing.

-7-

The second instance preferably defines the position of the element and/or the tension in the element when the element is closed in the patient.

The first instance preferably defines the position of the element and/or the tension in the element when the element is initially positioned and/or tensioned. One or more intervening instances may occur defining one or more other positions and/or tensions for the element.

The third and/or fourth aspects of the invention may further include any of the options, possibilities and features set out elsewhere in the application, including the first and second aspects of the invention.

Various embodiments of the invention will now be described, by way of example only, and with reference to the accompanying drawings in which:-

Figure 1 is a side view of fastener according to the first embodiment of the invention;

Figure 2 illustrates the side view perpendicular to the side view of Figure 1;

Figure 3 is a plan view of the fastener of Figure 1, from above;

Figure 4 is a cross-sectional side view of the fastener in the same direction as Figure 1, cross-sectioned along plane AA of Figure 2;

Figure 5 is a cross-sectional side view in the same direction as Figure 2, cross-sectioned along plane BB of Figure 1; and

Figure 6 is a perspective view of a fastener according to the present invention.

In order to correct spinal deformities and / or to provide support for a spine, support elements can be

-8-

introduced in to proximity with the spine. Support elements generally take the form of an elongate rod. To maintain the position of the supporting element relative to the spine, and hence to maintain the effectiveness of the supporting element, some form of fixing to the spine is required.

In certain situations it is possible to use pedical screws which are turned into the bone of the spine, to form the fixing. The pedical screws carry a head portion which forms a mounting location into which the supporting element is introduced and retained. Pedical screws require sufficient structurally sound bone at the specific location in question, however, for them to work successfully.

Hook style fixings are also known where a rigid hook style portion of the fixing is passed around a portion of the spine, the hook resisting movement in the direction that the support element pulls in use. Once again, the support element is mounted on the fixing at a mounting location provided in a head portion. Hook style fixings are only suited to attachment at certain parts of the vertebrae, have to be provided in a range of sizes and once again require local structural integrity for them to work successfully.

It is also known to attach support elements to the spine by wrapping wire around the supporting element and then wrapping the wire around a portion of the spine. The wire is tied off to retain the supporting element in position relative to the spine. A particular problem with such systems is that the wire once tied is difficult to adjust in tension. Such adjustments are often required, however, as tensioning adjacent wires to the support can relax the tension in a given wire. Thus a progressive process of tensioning wires is not feasible or at best very awkward to perform. In addition, the flexible nature of the wire and the difficulty in obtaining and maintaining high levels of tension in the wire during installation mean that such wires frequently slip relative to their engagement with

-9-

the supporting element in use. As a consequence, the supporting element is not fully maintained in position relative to the spine and the benefits and correct action of the support element are lost over time.

As illustrated in Figure 1, the fixing 1 of the present invention consists of a flat right cylinder base 3 from which two upright elements 5 and 7 respectively extend. The elements 5 and 7 defining between them a channel 9. The channel 9 has parallel sides 10 in its upper portion and a semi-circular profile 11 in its lower portion. The channel 9 extends through the fastener 1 from one side to the other between the two uprights 5 and 7.

Once fastened in position on the spine, in the manner described in more detail below, a supporting element (not shown) in the form of a circular cross-section rod is introduced into the channel 9. Forcing the rod down into the channel 9 by applying force directly to the supporting element and / or via a cap portion mounted on the fixing 1 (not shown), the rod is forced down until it sits in the semi-circular profile 11 at the base of the channel 9. The cap is introduced and retained in position by a threaded engagement with the screw threaded portion 13 provided on the top portion of the two uprights 5 and 7.

As a result of this configuration, the engagement between the supporting element and the fastener 1 is both controlled and reliable with the fastener's position relative to the supporting element being maintained by the force which can be applied through the cap.

To attach the fastener 1 to the spine, the fixing 1 is provided with a slot 15 in upright 5 and a slot 17 in upright 7, see Figures 2 and 5 respectively. Each slot 15 and 17 is formed from a first substantially semi-circular profile 19 and second substantially semi-circular profile 21, of lesser radius than the first. The two semi-circular profiles 19, 21 are joined by straight sides 23. This

-10-

overall profile of the slots 15, 17 means that the width of the slot tapers to a reduced level as the slot 15, 17 approaches the base 3 of the fixing 1. As can be seen in Figure 5, the lowest portion of the slot 15, 17, including semi-circular profile 21, extends below the level of the base 3. As a consequence, a groove 25 is formed in the base 3 which extends from one side of the fixing 1 to the other, see Figure 3.

To fasten the fixing on the spine, a wire is introduced through slots 15 and 17 and bent generally downwards towards the base 3. The base 3 is then positioned at the desired location on the spine and the wire is tied around the spine as firmly as possible. In this position, the wire will generally engage the bottom profile 21 of the groove 25, but may extend above the groove in some locations, notably the mid-portion. As the fixing is very firmly located as a discrete operation, the introduction of other fixings at adjacent locations does not effect the tension of such a fixing.

With the fixing located on the spine, the process is generally repeated for a number of other fixings at other locations of the spine. Once the desired number of fasteners have been located according to this method, (although at other locations pedical screws, hooks or standard wire type fastenings may be provided), the support element can be introduced. In general, the support element is introduced into proximity with the spine and then manoeuvred into position relative to one of the fixing. The fixing is then attached to the support element to locate it. The process is then repeated for the next fixing and so on. Where the supporting element is introduced into a fixing according to the present invention, the support element is forced down into the channel 9 as far as possible. A cap member, generally in the shape of a ring with an internal thread intended to cooperate with threaded portion 13 on

-11-

uprights 5 and 7 is then introduced and screwed down. The contact of the underside of this cap element with the support element forces the support element down further into the channel 9. Movement of the support element downward in turn forces the fixing wire downwards more fully into the groove 25 throughout its extent. Once located, the cap member serves to maintain the position of the support element in the channel 9 and the support element engages and serves to maintain the position of the wire in the groove 25, with the wire itself maintaining the position of the fixing 1 on the spine. All of the engagements are thus reliable and good vertebral body rotation control is provided. The support element may not be provided at its final position and/or tension when first retained in the fixing. It is readily possible to retain the support element, then release it to adjust its position and/or tension before retaining it firmly once more. In this way the implant can act as a temporary tensioner for the support and avoid the need to introduce instruments to the site for this purpose. The use of the cap which can readily be released and retightened facilitates this process. The cap can of course be fully removed in the adjustment process, but more usually will just be slackened off to an extent allowing movement of the support relative to the fixing whilst still being retainer in the channel.

The general configuration assumed is illustrated in Figure 6 where the fixing 1 is provided with the support member 30 extending on either side of the fixing and with the wire 32 gripped firmly in position and extending downward to wrap around the spine at an appropriate location. The retaining cap is omitted for clarity sake.

The relative dimensions of the wire used and the bottom slot profile 21 and groove 25 are configured to provide a snug accommodating location for the wire, particularly when deformed slightly by the downward force of the supporting

-12-

element. Similarly, the supporting element 30 and the lower profile 11 of the channel 9 are configured to form a snug fit.

As an alternative to using the external screw thread 13 to introduce and retain a cap, internal screw thread 27 can be used, the screw thread cooperating with an external thread on an alternative form of cap member.

-13-

CLAIMS:

1. A kit, for use in fixing an element relative to a spine, the kit comprising :
 - means for fixing a fixing to the spine;
 - a fixing providing an engagement location for the means for fixing the fixing to the spine and a location at which the element is retained;
 - means for retaining the element at the location on the fixing; and
 - an element.
2. A fixing for use in retaining an element relative to a spine, the fixing providing a location at which the element is retained and an engagement location for means used to fix the fixing relative to the spine.
3. A kit including a fixing or a fixing according to any preceding claim in which the fixing is provided with a base portion, preferably the base portion provides a surface which contacts the spine in use.
4. A kit including a fixing or a fixing according to any preceding claim in which the fixing has two portions extending from the base and the retaining location for the element is provided between the portions extending from the base.
5. A kit including a fixing or a fixing according to claim 4 in which the retaining location for the element is defined by a surface defined by the extending portions and base of the fixing.
6. A kit including a fixing or a fixing according to any preceding claim in which the retaining location is provided

-14-

in a channel through the fixing and the channel is open in the direction away from the base of the fixing.

7. A kit including a fixing or a fixing according to claim 6 in which the bottom of the channel has a corresponding profile/cross-section to the element retained.

8. A kit including a fixing or a fixing according to any preceding claim in which the fixing is provided with one or more portions which cooperate with means for retaining the element at the location.

9. A kit including a fixing or a fixing according to claim 8 in which the means for retaining the element at the location on the fixing close the open top of the channel upon introduction to the fixing.

10. A kit including a fixing or a fixing according to any preceding claim in which the engagement location is provided by a channel through the fixing through one or both of the portions extending from the base.

11. A kit including a fixing or a fixing according to claim 10 in which the channel is a closed channel closed by the upper part of the portions extending from the base.

12. A kit including a fixing or a fixing according to claim 10 or claim 11 in which the channel comprises an aperture in a first of the portions extending from the base and an aperture in the second of the portions extending from the base.

13. A kit including a fixing or a fixing according to claim 12 in which the apertures are linked by a groove in the base of the fixing.

-15-

14. A kit including a fixing or a fixing according to claim 13 in which the groove has a semi-circular cross-section or extends for less than half a circle in cross-section.

15. A kit including a fixing or a fixing according to claim 13 or claim 14 in which the groove has a cross-section configured to correspond to the profile of the means for fixing the fixing to the spine.

16. A kit including a fixing or a fixing according to any of claims 10 to 15 in which the aperture through one or both portions extending from the base of the fixing has a cross-section which tapers inwards towards the base.

17. A kit including a fixing or a fixing according to any preceding claim in which the means for fixing the fixing to the spine are one or more lengths of an elongate component, such as wire.

18. A kit including a fixing or a fixing according to any preceding claim in which it is tied to a part of the spine and/or wrapped around a part of the spine.

19. A kit including a fixing or a fixing according to any preceding claim in which the element is a support element for the spine and/or a stabilising element for the spine and/or a correcting element for the spine.

20. A method of fixing an element relative to a spine, the method comprising:

obtaining access to a location on the spine at which the element is to be fixed;

providing a fixing in proximity with the location and fixing the fixing to the location using means for fixing;

-16-

introducing the element into proximity to the fixing and retaining the element relative to the fixing.

21. A method according to claim 20 in which the element is released from the fixing subsequently, its position relative to the fixing and/or tension adjusted or varied and then be retained once more.

22. A method of treating at least a portion of a spine, the method providing two or more fixings according to the method of the third aspect and/or one or more fixings according to the third aspect and at least one alternative form of fixing, the method further providing an element which is introduced to the fixings and retained by the fixings, wherein the position of the element in a fixing and/or the tension in the element between two fixings is different between a first instance at which the element is retained relative to the fixing and a second instance at which the element is retained relative to the fixing.

23. A method according to claim 22 in which the position of the element and/or the tension in the element when the element is closed in the patient.

-1/1-

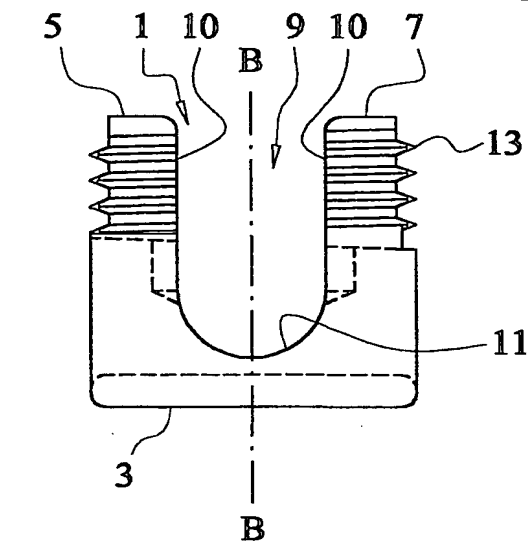


FIG. 1

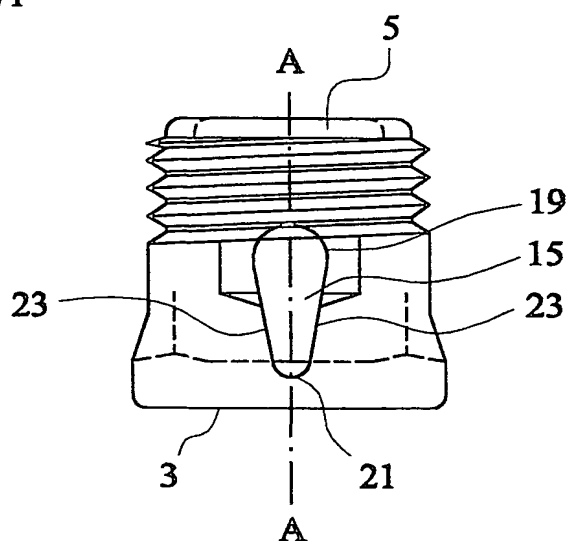


FIG. 2

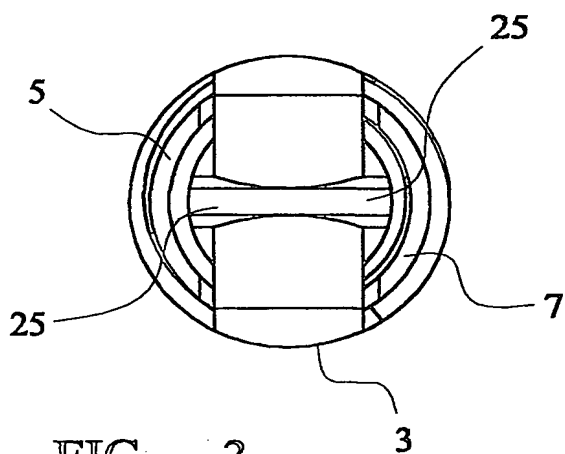


FIG. 3

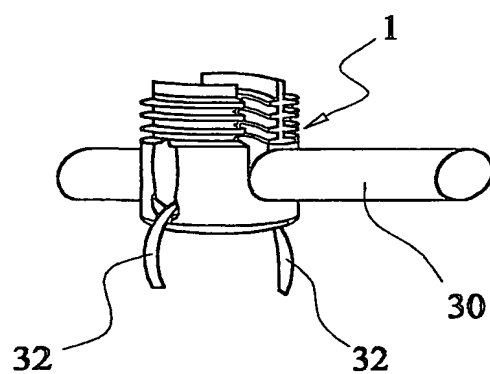


FIG. 6

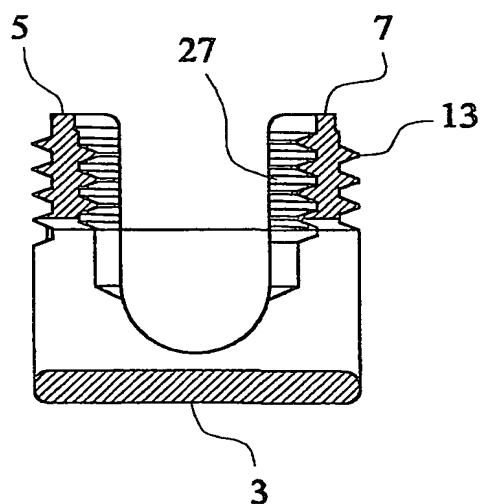


FIG. 4

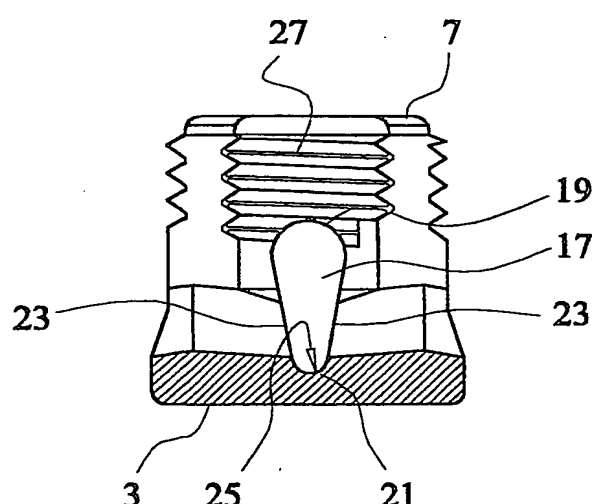


FIG. 5

INTERNATIONAL SEARCH REPORT

Internz Application No

PCT/GB 01/03522

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	WO 99 53855 A (DIMSO SA ;LASSEUR ERIC (FR)) 28 October 1999 (1999-10-28) abstract; figures 1,2 ---	1,2
X	US 5 403 314 A (CURRIER BRADFORD L) 4 April 1995 (1995-04-04) column 2, line 47 - line 52; figure 1 ---	1,2
A	WO 98 49960 A (AESCULAP JBS ;AMEIL MARC (FR); HUPPERT JEAN (FR); MARNAY THIERRY () 12 November 1998 (1998-11-12) abstract; figure 2 -----	1-19

☐ Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search

17 October 2001

Date of mailing of the international search report

24/10/2001

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern: I Application No

PCT/GB 01/03522

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